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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,408	08/23/2001	John H. Crowe	6829/60490 (800189-09)	2684

7590 11/07/2003

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,408	CROWE ET AL.	
	Examin r	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on th cover she t with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53,55-57,60-63 and 74-105* is/are pending in the application.

4a) Of the above claim(s) *76-105* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53,55-57,60-63,74 and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' amendment filed 9-12-03 has been entered. Claims 1-52, 54, 58, 59 and 64-73 have been canceled. Claim 53 has been amended. Claims 74-105 have been added. Claims 53, 55-57, 60-63 and 74-105 are pending. However, claims 76-105 are drawn to a process for **preventing a decrease in a loading efficiency gradient** in the loading of an oligosaccharide into the platelets by heating the oligosaccharide solution to the second phase transition temperature range to increase the loading efficiency of oligosaccharide into the platelets and **maintaining a positive gradient of loading efficiency to concentration of the oligosaccharide** in the oligosaccharide solution, which is considered new matter (discussed below) and a distinct invention from the elected invention of original claims 53-63. Therefore, claims 76-105 are withdrawn from consideration. Claims 53, 55-57, 60-63, 74 and 75 are considered.

Information Disclosure Statement

1. The information disclosure statement filed 9-12-03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The cited references on the information disclosure statement filed 9-12-03 can not be found in the referred Application No. 09/828,627, filed 4-5-01.

Specification

1. The amendment filed 9-12-03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The newly added paragraph (amendment, p. 2) on page 4 line 10 of the specification is considered new matter. The amendment indicates that page 18 lines 17-24 of the specification and Figures 3 and 4 support the added paragraph (amendment, p. 14). This is not found persuasive because Figure 3 shows higher loading efficiency of trehalose at 37oC as compared to 4oC and Figure 4 shows relationship between loading efficiency and trehalose concentrations but none of the cited disclosure support a process for **preventing a decrease in a loading efficiency gradient** in the loading of an oligosaccharide into the platelets by **maintaining a positive gradient of loading efficiency to concentration of the oligosaccharide** in the oligosaccharide solution. It is unclear what "loading efficiency gradient" and "positive gradient of loading efficiency" mean. The specification fails to specifically define those phrases. Further, the added paragraph recites "Loading the platelets with an oligosaccharide includes loading with a laoding efficiency ranging from about 45% to about 50% for the oligosaccharide solution having an oligosaccharide concentration ranging from about 20mM to about 30mM" but the specification, e.g. page 18 lines 17-24 of the specification and Figures 3 and 4, fails to provide support for the laoding efficiency ranging from about 45% to about 50% for the oligosaccharide solution having an oligosaccharide concentration ranging from about 20mM to about 30mM. The highest loading efficiency on Figure 4 is only about 48%. Thus, the newly added paragraph is considered new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 56, 57 and 60-63 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and is repeated for the reasons set forth in the preceding Official action mailed 5-16-03 (Paper No. 8). Applicant's arguments filed 9-12-03 have been fully considered but they are not persuasive.

Applicants cite page 8 lines 10 and 24-29 of the specification and argue that the specification provides support for claims 56, 57 and 60-63 (amendment, p. 11-12). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 5-16-03 (Paper No. 8). The cited disclosure in the specification only discloses the loading temperature of trehalose but fails to provide sufficient support that these temperature ranges are second phase transition temperatures. The specification only describes a second phase transition temperature range between 30°C and 37°C (see specification, pages 6, 9). Thus, claims 56, 57 and 60-63 remain rejected under 35 U.S.C. 112 first paragraph.

4. Claim 75 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants' amendment filed 9-12-03 necessitates this new ground of rejection.

Claim 75 specifies loading efficiency ranging from about 45% to about 50% for the trehalose solution having a trehalose concentration ranging from about 20mM to about 30mM. The specification fails to provide sufficient disclosure for the laoding efficiency ranging from about 45% to about 50% for the trehalose solution having an trehalose concentration ranging from about 20mM to about 30mM. The highest loading efficiency on Figure 4 is only about 48%. Thus, the phrase "loading efficiency ranging from about 45% to about 50% for the trehalose solution having an trehalose concentration ranging from about 20mM to about 30mM" is considered new matter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 53 and 55-57 remain rejected and claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie et al., 1998 (WO 98/14058) in view of Diniz-Mendes et al., 1999, (Biotechnology and Bioengineering, Vol. 65, No. 5, p. 572-578) and is repeated for the reasons set forth in the preceding Official action mailed 5-16-03 (Paper No. 8). Applicant's arguments filed 9-12-03 have been fully considered but they are not persuasive.

Claim 74 is newly added and specifies further maintaining a concentration of the trehalose in the trehalose solution at less than about 50mM.

Applicants argue that the claims recite various temperatures and temperature ranges for the second phase transition temperature range and Beattie or Diniz-Mendes does not teach the recited temperatures or temperature ranges (amendment, p. 12). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 5-16-03 (Paper No. 8). Claims 53, 55-57 and 74 do not recite the specific temperatures or temperature ranges as argued and Diniz-Mendes does teach that pre-exposure of cells to 40°C for 60 min and addition of trehalose can enhance survival rate of cells in freezing and freeze-drying treatments of cells. Further, Beattie does teach using trehalose at a range from 10mM to 30,000mM for preserving cells and using cells so preserved to restore function of the cells in a living subject (p. 23).

It should be noted that claims 76-105 are drawn to a distinct invention from the original claims 53-63 and will not be considered as discussed above.

Applicants argue that claim 53 is amended to read on loading trehalose by fluid phase endocytosis, which is patentably distinct from the teachings of Beattie and/or Diniz-Mendes

(amendment, p. 13). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 5-16-03 (Paper No. 8). As discussed in the preceding Official action mailed 5-16-03 (Paper No. 8), Diniz-Mendes teaches heating cells in a solution containing trehalose, and uptaking external trehalose via fluid phase endocytosis from the trehalose solution is part of the process step in heating the trehalose solution to a second phase transition temperature range. Further, Beattie teaches that passage of the trehalose through platelet cell membrane into the interior of the platelets could be due to transitory increase in membrane permeability and other means of incorporating trehalose into platelets to achieve an equivalent result will be readily apparent to those skilled in the handling of platelets (e.g. p. 8-9). Therefore, it would have been obvious for one of ordinary skill at the time of the invention to load trehalose into the platelets by uptaking trehalose from the trehalose solution by fluid phase endocytosis.

Oath/Declaration

It is acknowledged that the "Utility Patent Application Transmittal" filed 8-23-01 indicates Nelly Tsvetkova, Fern Tablin, and John Crowe are the inventors of the present application. The other three inventors, i.e. Willem Wolkers, Ann Oliver, and Naomi Walker, in the oath and declaration of parent application 09/828,627 have been removed.

Conclusion

No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

S Chen